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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,741	05/01/2001	Samuel T. Henderson	ACC.01	3451

25871 7590 07/13/2005  
SWANSON & BRATSCHUN L.L.C.  
1745 SHEA CENTER DRIVE  
SUITE 330  
HIGHLANDS RANCH, CO 80129

EXAMINER

SHARAREH, SHAHNAM J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/845,741

Applicant(s)

HENDERSON, SAMUEL T.

Examiner

Shahnam Sharareh

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Amendment filed on April 20, 2005 has been entered. Claim 11 is pending.

Applicant's arguments are moot in view of new grounds of rejection.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the recitation of "prodrugs of a medium chain triglyceride," in claim 11 was not disclosed in the specification of the instant application as originally filed. Although the applications described the use of medium chain triglycerides by itself, it did not describe the entire subgenus of "prodrugs of medium chain triglycerides" in the specification. Therefore, there is no basis for such limitation in the original disclosure.

During prosecution of an Application, if a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, Examiner should conclude that the claimed subject matter is not described in that application. See MPEP 2163. Thus, there does not appear to be a written description of the claim limitation "prodrugs of medium chain triglycerides." Accordingly, it is not

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understood what is the type of compounds that applicant is seeking protection for? The added claim is construed as new matter.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP Patent 06-287138 in view of Schmidl et al US Patent 5,504,072.

The instant claims are directed to methods of treating dementia comprising administering to a patient having dementia and having a diet wherein carbohydrate intake is not restricted an effective amount of prodrug of MCT.

JP publication provides application of MCT containing compositions to Alzheimer patients suffering from dementia who are not subject to a carbohydrate-restricted diet. (see abstract and para 0034-0036). JP '138 administers MCT to patients suffering from Alzheimer disease. (see abstract, para 0002). JP '138 clearly states that such patients are suffering from senile dementia caused by Alzheimer disease (see para 0002). The patients receiving the composition in JP '138 are not under a carbohydrate intake restriction because their therapy can contain sugar, and various types of mono- or polysaccharides (see para 0023-0024). In fact, JP '138 in para 0034 describes a diet regimen, which contains 54g of cornsarch and 10g of sugar. Thus, the subjects in JP '138 did not have a diet where carbohydrate intake is restricted. JP '138 does not specifically state that his compositions contain a prodrug of a MCT.

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Schmidl is used to show a normal nutritional compositions comprising lipid component comprising medium chain fatty acid triglycerides (MCT) and prodrugs thereof. Schmidl's fatty base contains glycerol or polyglycerols, various natural oils such as soy oil (col 4, lines 1-40; col 9, line 1-10) which are viewed to fall within the scope of the instant term "prodrug of MCT," because as evident by JP '138 glycerols of natural oils and fats are esterified enzymatically to form MCT. (see page ½ of JP '138).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to add additional natural oils, fatty acid esters or polyglycerols, as described in Schmidl, to the regimens of the JP' 138 to further enhance production of MCT in vivo, because as taught by JP publication, MCT improves or treats Alzheimer symptoms. Thus, the ordinary skill in the art would have expected to improve congestive behavior such patients with increasing such compounds that enhances production of MCT in vivo.

### ***Conclusion***

No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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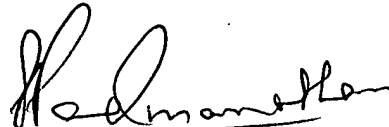
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SS

  
SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER